AMERICAN
ASSOCIATION
OF BLOOD BANKS

October 13, 1999

Dockets Management Branch (HFA 305)
Food and Drug Administration
5360 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Docket No 99-D-1878: Draft Guidance for Industry Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti HCV); (2) Supplemental Testing and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti HCV [Federal Register: June 22, 1999 (Volume 64, Number 19)].

To Whom it May Concern:

These comments supplement the comments filed by the Interoganizational HCV Lookback Committee (Committee) on August 16, 1999. The Committee represents the American Association of Blood Banks (AABB), America's Blood Centers (ABC) and the American Red Cross (ARC), and encompasses all of the volunteer blood collecting organizations and over 80 percent of the blood transfusion services in the United States.

The Committee would like to comment again on the proposed Draft Guidance in light of FDA's statements, both at the recent BPAC meeting and at the AABB FDA Liaison Meeting on October 1, 1999, that it does not expect to change the requirement to conduct lookback indefinitely if records are "readily retrievable."

FDA should be aware that simply defining the term "readily retrievable" is not an acceptable solution. FDA has already stated that it does not intend for blood establishments to devote inordinate time and resources to obtaining and reviewing these older records. The Committee believes, based on its members' intimate familiarity with such records, that any effort involving records that predate 1988 is almost certain to require the expenditure of inordinate time and resources.

FDA should also be aware of the widespread concern within our membership, which has been expressed by blood centers, and hospitals alike. Our institutional members see FDA's current position as contributing to the view that the agency neither understands nor appreciates the practical realities being faced by blood establishments and hospitals today. We would prefer to focus our ever-shrinking time on other measures that will provide greater benefit for patients such as leukocyte reduction. Spending time

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and resources attempting to find old information, knowing full well that the results of the record review will be extremely unlikely to reach the individual who may be at risk for HCV, diverts our efforts from more productive activities.

Contrary to the FDA's perception, the Committee believes that the Advisory Committee on Blood Safety and Availability (Advisory Committee) has carefully considered this matter and concluded that ten years was the outside limit practical for record review. Twice, the Advisory Committee has made such a determination, taking into account that (1) few records beyond that period will be available and (2) that such records as are available will provide a very limited return. The Advisory Committee also understood that the ten-year period should be defined as beginning on the date the requirement is initiated, not as of the date on which a given donor's initial reactive test was performed. Under this approach, whether the records are being reviewed for HCV 2.0/3.0 or for HCV 1.0 is rightly immaterial. The FDA may wish to consult the Advisory Committee directly to substantiate the Advisory Committee position.

Further, FDA has explicitly endorsed the concept of maintaining records for 10 years. In this draft guidance, Section III E states that ten years would be an acceptable time frame for maintaining records of the source and disposition of all blood and blood products.

Finally, it is again worth remembering that targeted lookback is not the only mechanism to make individuals aware of the their potential risk of HCV. Whether records of a donation are readily retrievable or not is largely irrelevant to the transfusion services we represent. They are faced with manual attempts to locate and contact a cohort of patients who have often died or moved. It is much more appropriate to reach those people through the general notification campaign than it is to ask hospitals already struggling with dwindling resources to make this additional effort. The general notification campaign being mounted by CDC specifically includes anyone transfused prior to 1992, and we anticipate that this will be far more successful in reaching individuals who may be at risk.

The yield of both types of notifications is unknown, but the limited data presented should not be ignored. Cost-effectiveness is a valid and important consideration, and data from the lookback as currently being done (back to 1988 only) should be evaluated before any additional record review is required. This would be entirely congruent with the Advisory Committee recommendation.

Again, we request that 1988 be the limit of record review for lookback, regardless of whether it is for HCV 1.0 or HCV 2.0/3.0. However, should FDA still decide to define "readily retrievable," we suggest that the definition be limited to include only electronically retrievable (computerized) records. In this context, such a limitation is the only practical solution for dealing with these older records. Computerized records are not only easier to locate, but are also more likely to be useful once they are retrieved. In contrast, we are aware of numerous instances of paper records that are stored in

unheated, unlighted, remote warehouses and of numerous instances in which microfiche records have faded or become illegible so that once they are retrieved, they are useless.

The Interorganizational Task Force on HCV lookback appreciates this opportunity to comment on the Draft Guidance, and encourages FDA to evaluate this issue carefully.

Any questions concerning this letter may be directed to Kay R. Gregory at 301-215-6522 or kayg@aabb.org.

Sincerely

Ramona Walker
Chair

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